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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,025	08/29/2000	Philip J. Larkin		6639

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EXAMINER
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KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/600,025	LARKIN ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 23 December 2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1-19,24 and 26-29 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-19,24 and 26-29 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

### **STATUS OF THE APPLICATION**

1. This Office action is in response to the Amendment and Remarks filed 23 December 2002.
2. Those rejections not specifically addressed in the Office action are withdrawn in view of Applicant's amendment and/or remarks.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Oath/Declaration***

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR § 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The instant Application has been filed under 35 USC § 371, in compliance with 35 USC §§ 365(c) and 120, but the Declaration in the file lists PCT/AU99/00004 under "Prior Foreign Applications(s)". In addition, the first line of the specification must be amended to indicate that -- This application is the National Stage of International Application No. PCT/AU99/00004, filed 7 January 1999 --. See 37 CFR § 1.78(a)(2)(i).

#### ***Drawings***

5. The drawings in this application are objected to by the Draftsperson as informal. See the attached PTO-948 form. Applicant is reminded that correction of the drawings cannot be held in abeyance, and that formal drawings are required in response to this Office Action as outlined in 37 CFR § 1.85(a). Failure to take corrective action within the set period will be considered non-responsive to this Office action.

***Claim Rejections - 35 USC § 112***

6. Claims 1-3, 7, 8, 28 and 29 remain rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2002. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive.

At claims 1-3, 7, 8 and 28, the phrase "plant material" is indefinite because it is unclear what is encompassed by this limitation. Applicant argues that amending the claims to recite the plant material as being a plant or explant as suggested in the previous Office action would be unduly limiting (page 8, 3<sup>rd</sup> paragraph of the Remarks). This argument is not found to be fully persuasive because of the breadth of the limitation as outlined in the previous Office action. In view of Applicant's arguments, the Examiner proposes the limitation -- transformable poppy plant material --.

At claims 28 and 29, line 1, the phrase "The transformed plant material" lacks proper antecedent basis in any one of claims 1 or 2, because said "plant material" is selected prior to transformation and neither claim 1 nor 2 recites "transformed plant material".

7. Claims 1-5, 7-19, 24, 26, 28 and 29 remain rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic *Papaver somniferum* comprising a medium comprising a buffering agent, does not reasonably provide enablement for a method of producing any *Papaver* or

*Eschscholtzia* species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. This rejection has been modified in view of Applicant's amendments to the claims. This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2002. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive.

Applicant argues that once the presence of the rise in pH is known, it is a matter of routine trial and experimentation to supplement the culture medium used with a suitable buffer at an appropriate concentration to prevent, reduce the rate of, or delay the rise in the pH and thereby implement the method of the invention. Applicant also argues that Applicant's have provided a solution which can be readily implemented and incorporated into conventionally known methods to thereby increase the probability of obtaining a favourable outcome, that is, obtaining a greater probability of success in regenerating poppy plants and recovering transgenic poppy plants (page 10, 1<sup>st</sup> paragraph of the Remarks). This argument is not found to be persuasive because the use of buffering agents in plant tissue culture media to regulate pH of said media for regenerating plants was know in the art at the time of Applicant's invention (see De Block 1990, Plant Physiology 93:1110-1116). What is at issue in the instant rejection is whether Applicant has taught one of skill in the art how to make and use the invention within the scope of the claims. The Examiner's opinion is that Applicant has only enabled a method of producing a transgenic *Papaver somniferum* plant by optimizing

the culture and regeneration medium for that plant. Applicant provides no evidence that the claimed method will work for producing any transgenic alkaloid producing poppy plant, said alkaloid producing poppy plant having been interpreted by the Examiner as any plant within the plant family Papaveraceae, because Applicant claims a method of producing transformed species within the genus *Eschscholtzia*. The Examiner reiterates that the art teaches that plant transformation remains an art because of the unique culture conditions required for each crop species (see Hanson *et al* 1999, Trends in Plant Science 4(6):226-230, specifically page 230, right column, first paragraph).

***Claim Rejections - 35 USC § 102***

8. Claims 1-9, 11-13, 16, 17, 24 and 26-29 remain rejected under 35 U.S.C. § 102(b) as being anticipated by Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin). This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2002. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive.

Applicant argues that half-strength MS and MS solid medium are conventional *unbuffered* culture media that have no buffering agents added to them for resisting changes in pH to any significant degree. Applicant argues that Yoshimatsu simply teaches the use of conventional culture medium and does not contemplate the effect of pH rise on transformation and regeneration of transformed plant material whatsoever.

Applicant also argues that a person of skill in the art would not consider the medium utilized in Yoshimatsu as being a buffer in the context of the present invention (page 11, 3<sup>rd</sup> paragraph of the Remarks). These arguments are not found to be fully persuasive because MS medium comprises ammonium nitrate and potassium nitrate in a predetermined ratio, which one of skill in the art would recognize as conferring a buffering effect on said medium. The issue that Yoshimatsu does not recognize this inherent property of MS medium in producing a transgenic alkaloid producing poppy plant is irrelevant to the instant rejection. See *Integra LifeSciences v. Merck*, 50 USPQ2D 1846, 1999 (DC SCalif), which teaches that even though the prior art does not recognize an inherent property of a taught method, the prior art does or can anticipate a claim that states such an inherent property.

9. Claims 24 and 26-29 remain rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin). This rejection is repeated for the reason of record as set forth in the last Office action mailed 30 January 2002. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive.

Applicant argues that Yoshimatsu does not teach or suggest transforming the poppy plant material in the presence of a buffering agent as now claimed (page 12, 1<sup>st</sup> paragraph of the Remarks). This argument is not persuasive because, regardless of the method of making, the transgenic alkaloid producing poppy plant of the instant

claims is anticipated or obvious over the teachings of Yoshimatsu. The method claimed and/or taught by Applicant does not distinguish the transgenic poppy plant from that of Yoshimatsu.

***Claim Rejections - 35 USC § 103***

10. Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin) in view of Bidney (U.S. Patent 5,932,782). This rejection has been modified from that of the previous Office action mailed 30 January 2002 in view of Applicant's amendments to the claims. Applicant's arguments filed 23 December 2002 have been fully considered but they are not persuasive.

The teachings of both Yoshimatsu and Bidney can be found in the previous Office action.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of Yoshimatsu using the teachings of Bidney to introduce exogenous nucleic acid(s) into an alkaloid producing poppy plant using microparticle bombardment. One of ordinary skill in the art would have had a reasonable expectation of success in modifying the teachings of Yoshimatsu using the teachings of Bidney.

Applicant argues that Bidney does not teach or suggest transforming alkaloid producing poppy plant material and/or regenerating a transgenic alkaloid producing poppy plant from such material in the presence of a buffering agent (page 12, 2<sup>nd</sup>

paragraph of the Remarks). This argument is not found to be persuasive because the microparticle bombardment method of Bidney would have been considered a functional equivalent to the *Agrobacterium* method taught by Yoshimatsu, and would not have been expected to lead to a teaching of unexpected results in introducing exogenous nucleic acid(s). The Examiner notes that Applicant does not teach microparticle bombardment to produce a transgenic alkaloid producing poppy plant *per se*.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.  
28 February 2003

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 1638

*David T. Fox*